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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,715	11/20/2001	Allan J. Cassell	SUPACHILL08	9576
7590 07/13/2004				
SIMON, GALASSO & FRANTZ, PLC. P.O. Box 26503 Austin, TX 78755-0503				
EXAMINER WARE, DEBORAH K				
ART UNIT 1651		PAPER NUMBER		

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/989,715	<b>Applicant(s)</b> CASSELL ET AL.	
	<b>Examiner</b> Deborah K. Ware	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 25-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)<br>6) <input type="checkbox"/> Other: _____. |
|--|--|

### **DETAILED ACTION**

Claims 1-40 are presented for examination on the merits.

#### ***Election/Restrictions***

Claims 25-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 23, 2004.

Applicant's election with traverse of Group I in the reply filed on April 23, 2004, is acknowledged. The traversal is on the ground(s) that there is no serious burden. This is not found persuasive because each group presents a different and distinct invention one from the other. A reference which may read on one invention may not read on the other, thus, the restriction is being maintained. There is a serious burden based upon this reason and those of record.

The requirement is still deemed proper and is therefore made FINAL.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-7, 13, 14-20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not appear to describe the super-cooling rates and temperatures, nor the heat absorption rates as claimed. Further, it is unclear from the specification that the complete laundry list of biologically active material has been properly described. Applicants are invited to point out in the specification wherein such support may be found for the rates, temperatures, ranges, active material, etc. Note the specific claim limitations in the claims as indicated above for the specific rates and temperatures for which are not described by the specification. Therefore, the specification fails to contain an adequate written description of the claimed invention using full, clear, concise and exact terms as set forth in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-24 are rendered vague and indefinite for the recitation of "A method comprising" wherein it is unclear what method is being carried out. The steps of the methods are identified but it unclear what is exactly intended to be carried out. Is it a cryopreservation method or lyophilization method, or some other type of freezing method for drying cells out or what? The metes and bounds of the claims are uncertain. The term "said pre-conditioned solute" recited in claims 2-6 and 15-19 as well as the

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term "the heat absorption rate" and "the pre-conditioned solute" of claims 6 and 20 lack antecedent basis. Thus, these claims are rendered vague and indefinite for these reasons as well. Also the language "for at least a portion of time" recited in claims 6 and 19 renders the claims indefinite because it is unclear how much time is intended. Thus, the metes and bounds of the claims can not be determined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4, 8, 10, 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Prien et al, (US Patent No. 6,615,592, effective filing date of January 2, 2001), cited on enclosed PTO-892 Form.

Claims are drawn to method comprising the steps of using a prechilled protectant to treat and freeze the treated material.

Prien et al teach method comprising the steps of using a prechilled protectant to treat and freeze the treated material. Note abstract and col. 4, lines 25-31, and 35-40, col. 6, lines 5-10, col. 7, lines 15-20, and col. 10, line 24.

The claims are identical to the teachings of Prien et al and are therefore, considered to be anticipated by the cited reference. Each of the claims appear to be

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explicitly taught by the cited reference and also the solution containing the cryoprotectant of Prien et al appears to be prechilled before the tissue is added thereto.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prien et al.

Claim 11 is drawn to glycerol as the choice of protectant.

Prien et al teach food grade protectants as the cooling solution.

The claim differs from Prien et al in that glycerol is not taught.

Hence, although glycerol is not specifically taught the claim would have been obvious to one of ordinary skill in the art at the time the claimed invention was made since glycerol is a well known food grade cryoprotectant and one of ordinary skill in the art would have been motivated by the teachings of Prien et al to select for any food grade protectant including glycerol. Thus, the claim is rendered prima facie obvious.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 5-7 and 14-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S.

Patent No. 6,681,581 in view of Prien et al, cited above.

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Claims are discussed above.

US Patent '581 cited above, patented claims teach a pre-conditioned solute as claimed herein. The identical rates and temperatures are carried out via super-cooling in order to produce the solute as claimed herein. Thus, it would have been obvious to one of ordinary skill in the art to use the solute as set forth in the patented claims in the method of Prien et al to provided for the instantly claimed methods. One of ordinary skill in the art would have been motivated by the cited combination of references in order to provide for the instant methods. The warming step is an obvious step to carry out for obtaining thawing as taught by Prien et al. Note col. 11, line 29. The claims are rendered prima facie obvious.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**DEBORAH K. WARE**  
**PATENT EXAMINER**

Deborah K. Ware  
July 10, 2004